

Tennessee Medical Laboratory Board Meeting
April 15, 2010
Minutes

Date: April 15, 2010

Time: 9:00 AM CDT

Location: Bureau of Health Licensure and Regulation
TN Department of Health
Heritage Place Iris Room
227 French Landing, Ground Floor
Nashville, TN 37243

Members Present: Norman Crowe, Chairman, Independent Lab Manager
Edward McDonald, MD Pathologist, Vice-Chairman
Trudy Papuchis, MD Pathologist Hospital Administrator
Pamela Bullock, MD Non-educator Pathologist
Royce Joyner, MD, Pathologist Educator
Darius Y. Wilson, MAT, Ed.D. Educator
Annie Washington, Medical Technologist
Cheryl Arnott, S.A.-Cytotechnologist
Diane Robbins, Medical Technologist
Christopher H. Seay, Medical Technologist

Members Absent: Steven R. Dickerson, M.D., Non Pathologist Physician
Gloria Jenkins, Citizen Representative
Hospital Administrator (Position Vacant)

Staff Present: Lynda S. England, Medical Technologist Consultant,
Director, TMLB
Jerry A. Gowen, Medical Technologist Consultant
Diona Layden, Assistant General Counsel, Advisory
Attorney
Elizabeth Miller, Director-Health Related Boards
Julia Daniels, Medical Technologist Consultant/
Surveyor, East Tennessee Regional Office
Taylor Carpenter, Medical Technologist
Consultant/Surveyor, East Tennessee Regional Office
Karon Hathcoat, Medical Technologist Consultant/
Surveyor, West Tennessee Regional Office
Onezean Otey, Jr., Medical Technologist
Consultant/Surveyor, Middle Tennessee Regional Office
Karen Hargrove, Medical Technologist,
Consultant/Surveyor, Middle Tennessee Regional Office

Staff Absent: Mary Hamblen, Medical Technologist
Consultant/Surveyor, West Tennessee Regional Office

**Minutes
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CLIA Representative: Sandra Bogard, CLIA Manager

Quorum: A sufficient number of board members were present to constitute a quorum

Call To Order: The meeting was called to order at 9:02 AM CDT by Mr. Crowe.

Presiding Officer: The meeting was conducted by Mr. Crowe

Introductions: Mr. Crowe introduced Dr. Royce Joyner, Pathologist Educator as a new appointed Board member.

Mr. Crowe introduced Ms. Diona Layden, Assistant General Counsel, Advisory Attorney.

Mr. Crowe introduced the new surveyor for the MTRO, Karen Hargrove.

Mr. Crowe asked the board members to introduce themselves to the audience and state the interest group they represented. Non-Board members also made their introductions.

Amendment to the Agenda: Item 11, Tab 17-A, FISH, Conference Call with Dr. Roger Hubbard, will be conducted at approximately 9:30 AM.

Item 17, Tab 22, Ms. Allen, Assistant Commissioner will discuss the financial statement, at approximately 9:45AM, after the conference call on FISH.

Item 21, Tab 26, Licensure for Director, Dr. Yung, moved forward on the agenda.

Approve Minutes:

P & E A motion to approve the January 13, 2010 Personnel & Education Committee minutes was made by: Mr. Seay
Second: Dr. McDonald

Motion approved

Board The minutes from the January 14, 2010 board meeting were approved on a motion made by: Mr. Seay
Second: Dr. McDonald

Motion approved

Board Reports:

**Ratification of P&E Committee
Minutes:**

Ms. Washington reported on the actions of the Board's Personnel & Education Committee meeting, April 14, 2010.

Motion: Mr. Seay

Second: Dr. McDonald

The report was approved as given.

Contested Cases

No contested cases were presented during this meeting.

**Consent, Agreed,
Compliance Orders**

Consent

There was no consent orders presented during this meeting.

Agreed

There were no agreed orders presented during this meeting.

Compliance

There was an order of compliance presented during this meeting. The Petitioner was April R. Rogers. Ms. Layden presented a packet of information for review.

Dr. McDonald requested Ms. Layden summarize the compliance order. Ms. Layden did so.

Motion to ratify the Order: Dr. McDonald

Second: Dr. Papuchis

Motion to ratify the Order approved.

**Letters of
Reprimand**

There were no letters of reprimand presented during this meeting.

**Item 21, Tab 26, Licensure for
Director, Dr. Jar-Fee Yung**

Applicant for Director of Cytogenetics.

Degreed in 1974, Biology, University of California, Berkley. Awarded the Ph.D in 1984, Molecular Biology, University of California, Los Angeles.

Certified by the American Board of Cytogenetics (ABMG) and considered a diplomat in good standing. She met examination qualifications and has passed both the general and specialty exams.

Dr. Yung did not have post-graduate training and was grandfathered by the ABMG based upon work experience. This work experience at Evanston Hospital and the University of Illinois has not been verified. This was in 1987 and was the last year of grandfathering without a formal program.

Two fingerprint reports were rejected due to poor quality and Dr. Yung was to have those scanned here in the State.

Clear and active Director's license in the State of Florida.

Motion to approve licensure: Dr. McDonald
Second: Mr. Seay

Motion to approve licensure approved.

**Tennessee Professional
Peer Assistance Program
(TNPAP):**

The report was given by Lynda England for Mike Harkreader, MA, RN * TNPAP State Director.

The TNPAP statistical report for the period July 1, 2009 To March 31, 2010, stated this advocacy agency was currently monitoring eight (9) individuals.

During this period there were five (5) referrals. Referral sources, Board four (4) and Other one (1). Four (4) individual signed a monitoring agreement and one (1) individual did not need a monitoring agreement.

Discharges, two (2) individual successfully completed their monitoring agreement, one (1) monitoring not necessary and One (1) individual that was non-compliant, could not come into compliance and was reported to the Department of Health. The other five (5) individuals were under contract before July 1, 2009.

Motion to accept this report: Dr. McDonald
Second: Annie Washington

Report Approved.

A copy of the report is attached to the minutes.

Note: Review of TNPAP materials via internet counts as clock hours toward continuing education credits. A certificate of completion documenting review of these materials can be completed at the end of the internet session. Internet site: www.TNPAP.org

Ratifications: The following items were presented to board members for ratification per staff, state surveyor or facility request:

Exemptions for point of care testing procedures (POCT) in a licensed Facility

**Memorial Hospital
Chattanooga**

Ann Durham, MT, supervisor of POCT, representing Vicki Burger, Laboratory Administrative Director, requested an extension to an existing exemption to allow Respiratory Therapist to use the I-Stat on the Code Team, Rapid Response Team and in the Emergency Department, performing Electrolytes, Gasses and Ionized Calcium.

Motion to approve: Dr. McDonald
Second: Dr. Bullock

Motion approved

POCT Exemption Requests were interrupted in order to accommodate time constraints presented by the scheduled conference call.

**Item 11, Tab 17-A, FISH,
Conference Call with Dr. Roger
Hubbard**

There was a conference call between the Board Members and Dr. Roger Hubbard, Molecular Pathology Laboratory, Maryville, TN in regard to definition of the pre-analytical stage of FISH testing and the need for licensure.

There was general discussion, questions and answers regarding FISH testing and what might constitute a pre-analytical phase of the testing and if this phase of the testing would need licensed or non-licensed personnel to perform.

Dr. Hubbard had previously submitted a document to the Board of his recommendation on the phases of the testing that would justify a non-licensed person performing that phase. (Document attached to the minutes).

At the conclusion of the conference call, Mr. Crowe extended the thanks of the Board for Dr. Hubbard's participation in this topic.

Motion for staff and legal to draft a policy regarding the

pre-analytical and analytical aspects of FISH testing.
The four sitting pathologists on the Board would provide input and review: Dr. McDonald
Second: Mr. Seay

Ms. Miller interjected that there may be a problem with sunshine rules when too many Board members are involved.

Motion was amended as follows:
Motion for staff and legal to draft a policy regarding the pre-analytical and analytical aspects of FISH testing.
Dr. McDonald will provide input and review:

Motion approved.

**Quarterly Financial Statement
Christy Allen,
Assistant Commissioner, BHLR.**

Ms. Allen presented the Quarterly Financial Statement to the Board. It was reported that the Board's revenues far exceeded its expenditures, thus the Board meets the statutory requirement of self sufficiency.

Ms. Allen reviewed several line items that needed further explanation and clarification. These items were the allocations of payroll and rent; with further explanation as to how rent is calculated.

Mr. Crowe extended the thanks of the Board for the quarterly financial statement to Ms. Allen.

Motion to accept the report as presented: Dr. McDonald
Second: Mr. Seay
Motion approved.

A recess was called by the Chairman at 10:40 AM and to reconvene at 10:55 AM.

The Chairman called the meeting back to order at 10:55AM.

**Exemptions for point of
care testing procedures
(POCT) in a licensed
Facility (Continued)**

**Memorial
Northpark
Hixson**

Ann Durham, MT, supervisor of POCT, representing Vicki Burger, Laboratory Administrative Director, requested an exemption to allow Respiratory Therapist to use the I-Stat on the Code Team, Rapid Response Team and in the Emergency Department, performing Electrolytes, Gasses and Ionized Calcium.

There were questions regarding correlation studies, QC

and any previous exemptions. Current correlation studies will need to be in place prior to any exemption.

Motion to table: Mr. Seay

Second: Dr. McDonald

Motion to table approved

**Baptist Hospital
Nashville**

Dr. McDonald recused himself from the discussion.

Judy Davis, Laboratory Quality Compliance Manager Requested an extension of a previous exemption to allow Registered Nurses and Licensed Practical Nurses to perform and report sodium, chloride, potassium, glucose, creatinine, BUN, hematocrit and prothrombin time/INR utilizing the I-Stat in the surgical services area of the hospital.

Motion to approve: Mr. Seay

Second: Dr. Papachis

Motion approved

**Methodist
University
Hospital
Memphis**

Dr. Joyner recused himself from the discussion.

Harriet Bateman, POCT Coordinator, requested an extension to an existing exemption to allow Registered Nurses and Licensed Practical Nurses to perform and report Protime/INR testing using the I-STAT in the Coumadin Clinic.

Motion to approve request: Mr. Seay

Second: Dr. Papachis

Motion approved

**UHS/LabCorp
Knoxville**

Mr. Crowe recused himself from the discussion and passed the gavel to the Vice-Chair, Dr. McDonald.

Ms. Deborah Headrick, Point of Care Coordinator, requested an exemption to allow Registered Nurses, Respiratory Therapists, Perfusionists, Certified Vascular Techs, Registered Radiology, Certified Registered Nurses and Anesthetists to report Activated clotting times (ACT's) using the I-Stat (presently using the Hemochron System), in the following locations: Cardiovascular Lab, Cardiovascular Intensive Care Unit, Surgery Suites, Surgical Critical Care Units,

Interventional Radiology, Surgery Post-Op Unit, 8 East-
Medical Cardiology and Medical Critical Care Units

Motion to approve request: Dr. Bullock
Second: Mr. Seay

Motion approved

The gavel was returned to the Chairman, Mr. Crowe

**Direct More Than Three (3) Labs
Rule 1200-6-3-.13(5) Medical Lab
Facilities:**

No requests were presented to the Board during the
meeting.

**Discuss, review, and take action, if
needed, regarding but not limited
to the following:**

Necessity of Licensure:
Single Laboratory/Shared License
Morning vs. Evening Operations
Jamie Suzanne Drown
Attorney-At-Law
Bradley, Arant, Boult, Cummings, LLP

Ms. Layden said she had spoke with Jamie Drown and
had decided not to pursue this request.

**Establish Board Policy: Non-
Compliance with 90 Day Cure
Period in regard to HRB Audit
Process.**

The draft policy was presented to the Board for review
and or approval.

Motion to approve as the Board's Policy Statement:
Dr. Papachis
Second: Ms. Robbins

Motion approved.

**Exemptions to monthly director
visits for:**

**Lifblood-Madison Avenue,
Memphis, TN
Lifblood-US Hwy 64 STE 109,
Memphis, TN
Lifblood-W. Poplar-Collierville,
TN
Lifblood-Poplar-Memphis, TN
Lifblood-Exeter Road-
Germantown, TN
Lifblood-Hwy 51 N.-Covington,
TN**

A copy of the adopted policy is attached to the minutes.
Sandra Dorothy, Quality Assurance Coordinator for
Lifblood, requested an exemption from the minimum
monthly visits by the medical director.

Discussion regarded the limited test menu, hemoglobin
and/or hematocrit, the need for monthly or other interval
visits by the medical director and the rules governing
those visits (Rule 1200-06-03-.14 (6)).

Under the Rules 1200-06-03-.15 SPECIAL
REGULATIONS FOR ASTC, BLOOD DONOR
CENTERS, AND PLASMAPHERESIS CENTERS, (2)
provision is made for exceptions to the requirements of
1200-06-03-.14.

It was discussed that as of May 1, the facilities would no longer be performing hematocrit testing in deference to Hemocue Hemoglobin testing a waived test procedure. If only waived procedures are performed there is no requirement for State licensure, thus the request would become a moot point.

A motion was made to grant an exception to the medical director from Rule 1200-06-03-.14(6) making monthly visits; under authority of Rule 1200-06-03-.15(2):

Dr. Papachis

Second: Dr. Wilson

The floor was open for discussion on the motion. Dr. Wilson questioned as to a plan of visitation by the medical director. Ms. Dorothy replied that it was her understanding that the medical director would visit if a need was identified requiring a visit. Various methods of Director/Laboratory interactions were discussed.

A vote on the motion was called by the chairman. There were two nay votes, Ms. Washington and Ms. Robbins.

Motion was approved by the majority.

Questions immediately arose as to the motion and what the Board members had voted upon.

Parliamentary procedure: Ms. Layden, legal counsel and acting parliamentarian, spoke that given the confusion by Board members that the motion should be restated in its entirety, rescinding the previous motion in its entirety.

Dr. Papachis made a motion to rescind the previous motion and moved that this lab be granted an exception to the minimum monthly medical director visits Rule 1200-06-03-.14(6); based upon the authority of Rule 1200-06-03-.15(2):

Second: Dr. Wilson

Ms. Robbins made a motion to amend the previous motion on the floor to include that on-site quarterly visits shall be made:

Second: Ms. Washington

The maker of the original motion and the second both agreed to the amendment.

The floor was open for discussion

A call for the vote on the motion as amended:

Motion approved.

The chairman called for a 10 minute break at 12:30 PM.

The chairman called the meeting back to order at 12:45 PM.

**Personnel Requirements: Flow
Cytometry Testing Molecular
Diagnostics**

No action was taken on this agenda item.

**Additions/Deletions to the Board's
Waived Test List**

Nothing to present

Receive reports and/or requests

Board Director's Report

Ms. England reported the following:

A statistical report of the activities of the administrative office.

A new newsletter will be forthcoming later this year after the legislative session.

The Board position of Hospital Administrator is vacant and a replacement is being sought. Dr. Papachis' Board appointment has expired but continues to be present at the Board meetings until her appointment is extended or a replacement named.

The rules continue to be studied regarding

Motion to accept report: Mr. Seay

Second: Ms. Robbins

Report accepted.

Reinstatement of License

No request for the reinstatement of a facility license was presented for review during the meeting.

Office of General Counsel

Ms. Layden reported that there was one (1) case in her office from Investigations for further review. Also, as previously noted, Rules continue to be reviewed.

Motion to accept report: Ms. Washington

Second: Mr. Seay

Report accepted.

**Bureau of Investigations
(BIV) Report
Juanita Stone: Disciplinary
Coordinator**

Ms. England presented the report, first quarter 2010, in the absence of Ms. Stone.

Investigative Report Cumulative 2009

The following actions were reported to board members:

Currently open Complaints: Fifteen (15)

Total Closed Complaints: Zero (0)

Allegation with activity:

Drug-Related 1

Unprofessional Conduct: 1

Other (Advertising) 1

Geographical Locations:

West 1

Middle 2

All complaints must go through the Bureau of Investigations for review before they are closed or referred to the Office of General Counsel.

Motion to accept report as presented: Mr. Seay

Second: Ms. Washington

The report was accepted as presented

**Reports/Discussion Regional
Surveyors**

ETRO Report

East TN Regional Office: Julia Daniels

Unsatisfactory/ Unsuccessful Proficiency Testing:

The East Tennessee Regional Office reported Zero (0) unsuccessful proficiency testing events for the first quarter of 2010. (Two out of Three PT Events or Two in a Row)

Licensed laboratories with a second occurrence of unsuccessful proficiency testing events for the first quarter of 2010. (Three out of four or three in a row): Zero (0).

Complaint Investigations:

The East Tennessee Regional Office conducted Zero (0) investigation(s), substantiated, for the first

quarter of 2010.

MTRO Report

Middle TN Regional Office: Onezean Otey, Jr.

Unsatisfactory/Unsuccessful Proficiency Testing:

The Middle Tennessee Regional Office reported One (1) unsuccessful proficiency testing events for the first quarter of 2010. (Two out of Three PT Events or Two in a Row)

Licensed laboratories with a second occurrence of unsuccessful proficiency testing events for the first quarter of 2010. (three out of four or three in a row): zero (0).

Complaint Investigation:

The Middle Tennessee Regional Office conducted Zero (0) complaint investigation(s) for the first quarter of 2010.

WTRO Report

West Tennessee Regional Office: Karon Hathcoat

Unsatisfactory /Unsuccessful Proficiency Testing:

The West Tennessee Regional Office reported Zero (0) unsuccessful proficiency testing events for the first quarter of 2010. (Two out of Three PT Events or Two in a Row)

Licensed laboratories with a second occurrence of unsuccessful proficiency testing events for the first quarter of 2010. (three out of four or three in a row): zero (0).

Complaint Investigations:

There was zero (0) complaint investigations conducted for the first quarter of 2010.

Motion to accept regional surveyor's report as presented: Mr. Seay

Second: Dr. McDonald

Report accepted as presented

Board Ratification of Laboratory Initial License

Memphis Pathology
Laboratory/AEL Wartburg
1238 Knoxville Hwy Suite A
Wartburg, TN 37887

Dr. Joyner recused himself from the discussion.

Medical Director: Robert S. Richmond, MD
Anatomic/Clinical
Pathology

Category: Clinical Laboratory

Specialties: Hematology, Clinical Chemistry, Urinalysis,
Influenza Screen, KOH, Wet Prep, Strep A Antigen Screen,
UCG, Prothrombin Time

Surveyor: Taylor Carpenter, Consultant II
East TN Regional Office

Motion to approve License: Dr. Bullock

Second: Mr. Seay

License Approved

Vanderbilt 100 Oaks
Diagnostic Laboratories
719 Thompson Lane,
Suite 23200
Nashville, TN 37204

Ms. Arnott recused herself from the discussion

Medical Laboratory Director: Fritz F. Parl, MD
Anatomic/Clinical
Pathology

Category: Clinical Laboratory

Specialties: Bacteriology, General Immunology (limited),
Clinical Chemistry, Urinalysis, Endocrinology, Hematology,
Cytology and Clinical Cytogenetics.

Surveyor: Onezean Otey, Jr., Consultant II
Middle TN Regional Office

Motion to approve License: Dr. Bullock

Second: Dr. McDonald

License Approved.

Spectrum Laboratory
Network-Chattanooga PSC
1301 Mc Callie Avenue
Chattanooga, TN 37404

Medical Director: Janice Hessling, MD, Ph.D
Anatomic/Clinical
Pathology, Cytopathology

Category: Collection Station

Surveyor: Julia Daniels, Consultant II

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East TN Regional Office

Motion to approve License: Dr. McDonald
Second: Mr. Seay

License Approved.

**One Stop Lab Testing
1990 Old Fort Parkway,
Suite A
Murfreesboro, TN 37129**

Medical Director: Heidi Lakes, MD
MD Family Medicine

Category: Collection Station

Surveyor: Onezean Otey, Jr., Consultant II
Middle TN Regional Office

Motion to approve License: Dr. Wilson
Second: Ms. Washington

License Approved.

**Mid-South Community
Pathology
1805 N. Jackson Street,
Suite 7
Tullahoma, TN 37388**

Medical Director: Kenneth S. Piech, MD
Anatomic/Clinical
Pathology

Specialty: Pathology (Histopathology & Oral
Pathology)

Surveyor: Onezean Otey, Jr., Consultant II
Middle TN Regional Office

Motion to Approve License: Mr. Seay
Second: Dr. Bullock

License Approved.

**Physicians Plasma Alliance,
LLC
124 Old Gray Station Road
Gray, TN 37165**

Medical Director: Bruce Boggs, MD
Family Medicine

Specialty: Blood/Plasma Donor Center (HCT and Total
Protein)

Surveyor: Julia Daniels, Consultant II
East TN Regional Office

Motion to Approve License: Mr. Seay
Second: Ms. Washington

License Approved.

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Nodality, Inc.
405 Duke Drive, Suite 240
Franklin, TN 37067

Medical Director: Katherine S. Hamilton,
MD
Anatomic/Clinical
Pathology, Hematology

Specialty: General Immunology (FISH)

Surveyor: Onezean Otey, Jr., Consultant II
Middle TN Regional Office

Motion to Approve License: Dr. McDonald
Second: Mr. Seay

License Approved.

Other Business

For Informational Purposes, Information was given
pertaining to JCAHO and Academic Documentation.
CLIA accepts copies of the State License.

Two FAQs were recently posted on the JCAHO
Website. One has a paragraph that states,

“When there is a State personnel licensure requirement,
evidence of the individual's State license is acceptable to
demonstrate their academic achievement. No further
academic documentation (diplomas, degrees, transcripts)
is required. This applies to physicians (MD, DO, DPM,
DDS), midlevel practitioners, and testing personnel.
Note that a State license must be primary source verified
per Joint Commission standard HR.01.02.05. Also,
evidence of laboratory credentials formerly granted by
the federal government under the Department of Health
Education and Welfare (HEW) are also acceptable and
no further academic documentation is required.”

The following links may help alleviate some of the
questions and concerns.

http://www.jointcommission.org/AccreditationPrograms/Hospitals/Standards/09_FAQs/HR/Evidence+of+Qualifications.htm

[http://www.jointcommission.org/AccreditationPrograms/Hospitals/Standards/09_FAQs/HR/Primary+Source+Ve](http://www.jointcommission.org/AccreditationPrograms/Hospitals/Standards/09_FAQs/HR/Primary+Source+Verification.htm)

rification.htm

Statement of Next Meeting

The next Board Meeting will be July 15, 2010, and will begin at 9 AM CDT in the Iris Room, Ground Floor, Heritage Place, 227 French Landing, Metro Center, Nashville, TN. 37243.

Record of Adjournment

With no further business to discuss, the meeting was adjourned at 1:15 PM CDT on a motion properly presented by Dr. Bullock seconded by Dr. McDonald.